

Remarks/Arguments:

As a preliminary matter, it is noted with appreciation that the Examiner has withdrawn the claim rejections under 35 U.S.C. § 112 as well as the claim objections based on informalities.

Double Patenting

Claims 20, 22-25, 27-33, 39, 41, 54, and 55 stand rejected under the judicially created doctrine of obviousness-type double patenting based on U.S. Patent No. 5,800,508.

To overcome this rejection, a Terminal Disclaimer is submitted herewith. Withdrawal of the double patenting rejection is respectfully requested.

Claim Rejections -- 35 U.S.C. § 102

Claims 20, 22-24, 31-33, 41, 54, and 55 stand rejected under 35 U.S.C. § 102(e) as anticipated by Cragg (U.S. Patent No. 5,405,377).

Independent claim 54 recites that "each of said hoops [are] oriented in a plane substantially perpendicular to the longitudinal axis of the stent." This substantially perpendicular hoop configuration is distinguishable from Cragg's helical configuration, and the distinction between these configurations was identified in Applicants' specification.

Specifically, at page 9, lines 13-19 of Applicants' specification, reference is made to the helical configuration disclosed in EP-A-0556850 (copy enclosed), which is the European patent that corresponds to the cited Cragg reference. The specification further recites that, as an alternative to Cragg's helical configuration, "the wire may be of an entirely novel configuration, namely one in which the wire forms a plurality of hoops such that the plane of the circumference of each hoop is substantially perpendicular to the longitudinal axis of the stent."

The Office Action cites Figures 1-4 and column 2, line 40, through column 3, line 4, of Cragg. The cited portions of Cragg fail, however, to disclose hoops oriented in a plane substantially perpendicular to the longitudinal axis of the stent.

In Paragraph 2 of the "Response to Arguments," the Office Action also relies on a definition of "substantial" ("being largely but not wholly that which is specified"), but reaches

an erroneous conclusion that the term "substantially perpendicular to the longitudinal axis" means "greater than 50% perpendicular to the longitudinal axis." Applicants respectfully disagree. Even accepting the definition of "substantially" solicited in the Office Action *arguendo*, the term "substantially perpendicular" would mean "largely but not wholly perpendicular to the longitudinal axis." There is no justification provided in the Office Action or in the dictionary definition for the adoption of a "greater than 50%" interpretation of the term "substantially"--such interpretation appears to contradict the dictionary definition provided.

Additionally, by identifying a substantially perpendicular hoop configuration as an alternative to the helical configuration of Cragg (i.e., by distinguishing the helical configuration disclosed in corresponding EP-A-0556850), the term "substantially perpendicular" excludes such a helical configuration.

For the foregoing reasons, Cragg fails to anticipate claim 54 or claims 20, 22-24, 31-33, 41, or 55, each of which is directly or indirectly dependent upon claim 54. Accordingly, withdrawal of the rejection based on Cragg is respectfully requested.

Claims 20, 22-24, 31, 54-57 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Fontaine (U.S. Patent No. 5,370,683).

Claim 54 recites that "each of said hoops [are] oriented in a plane substantially perpendicular to the longitudinal axis of the stent" as mentioned previously. Claim 56 recites that "the vertices of each hoop . . . lie in a common plane perpendicular to the axis of the tubular member."

The Office Action cites Figures 6, 9, 10, and 14 as well as lines 42-56 of column 4 of Fontaine. Fontaine fails, however, to disclose that *each* of the hoops is oriented in a plane substantially perpendicular to the longitudinal axis of the stent (as recited in claim 54) or that the vertices of *each* hoop lie in a common plane perpendicular to the axis of the tubular member (as recited in claim 56). Instead, Fontaine teaches (at Column 4, lines 13-15, for example) an expanded wave form wrapped, *in a spiral*, around a mandril.

In Paragraph 3 of the "Response to Arguments," the Office Action again relies on an erroneous conclusion that the term "substantially perpendicular to the longitudinal axis" means "greater than 50% perpendicular to the longitudinal axis." For the same reasons set forth above in connection with the Cragg reference, Applicants respectfully disagree. It is further

noted that claim 56 recites "perpendicular" as opposed to "substantially perpendicular," and the strained definition of "substantially" proposed in the Office Action therefore does not apply to claim 56.

In Paragraph 3 of the "Response to Arguments," the Office Action also relies upon Figures 13-16 of Fontaine, stating that those figures "clearly show embodiments in which the vertices align in a common plane perpendicular to the longitudinal axis of the stent." Applicants respectfully disagree--such an interpretation of those figures contradicts the disclosure of Fontaine, which appears to be limited to a spirally wound configuration. See, for example, the general description of the preferred embodiment at column 7, lines 55-59 ("[T]he hoops, end component sections, as well as the spiral shape of the stent itself are oriented to inhibit longitudinal growth of the stent during radial expansion.").

For the foregoing reasons, the Fontaine reference fails to anticipate independent claims 54 and 56 as well as claims 20, 22-24, 31, 55, and 57, which are directly or indirectly dependent upon independent claims 54 and 56. Accordingly, withdrawal of the rejection based on Fontaine is respectfully requested.

Claims 20, 22-25, 39, 43, 44, 47 and 54-55 stand rejected under 35 U.S.C. § 102(b) as anticipated by Wolff (U.S. Patent No. 5,104,404).

Claim 54 recites "means for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop." For illustration purposes, the securing means may optionally comprise a loop element of a suture material to tie the juxtaposed apices together. See page 10, lines 16-23 of this application, for example.

Wolff relates particularly to arteries which have a curved portion, curved and recurved portions, changes in diameter, which are difficult to obtain using existing stents. See column 1, lines 14-19 of Wolff. Accordingly, Wolff discloses stent segments flexibly connected by a hinge. See Wolff at column 1, lines 45-47. According to Wolff, this maintains a space between adjacent segments as established by the hinge lengths. See Wolff at column 1, lines 47-52, for example. This spacing is illustrated by Wolff in Figs. 1, 3, 4 and 6.

The Office Action fails to identify any disclosure in Wolff of such a means for securing an apex of one hoop to a *juxtaposed* apex of a neighboring hoop. Specifically, Wolff fails to disclose means for securing an apex of one hoop to a *juxtaposed* apex of a neighboring hoop.

In fact, Wolff teaches away from such a configuration by touting the benefit of hoops spaced apart by hinge lengths. See Wolff at column 1, lines 47-52 ("This approach not only allows use of unequal diameter stent segments as the artery diameter changes, and permits articulation between adjacent stent segments, but also maintains the spacing between adjacent segments as established by the hinge lengths."). See also Wolff at column 3, lines 55-62 ("[H]aving the hinge spacing located on the outside portion of the articulated stent 10 allows these inner edges to close.").

For the foregoing reasons, Wolff fails to anticipate claim 54 and claims 20, 22-25, 39, 43, 44, 47, and 55, each of which is directly or indirectly dependent upon claim 54. Accordingly, the withdrawal of the rejection based on Wolff is respectfully requested.

Claim Rejections -- 35 U.S.C. § 103

Claims 45, 46, 48, and 49 stand rejected as being unpatentable based on a proposed combination of Wolff with Piplani (U.S. Patent No. 5,824,039).

It is respectfully submitted that the proposed combination of Wolff with Piplani, even if such a combination were suggested, fails to establish *prima facie* obviousness. Specifically, even the proposed combination of Wolff and Piplani fails to disclose or suggest means for securing an apex of one hoop to a *juxtaposed* apex of a neighboring hoop. As discussed previously, Wolff teaches away from this feature recited in claim 54 (upon which each of claims 45, 46, 48, and 49 is dependent). Because Piplani fails to compensate for the deficiency of Wolff, the hypothetical combination itself is inadequate to establish *prima facie* obviousness.

Additionally, none of the passages of Wolff and Piplani cited in the Office Action suggests a radiopaque element attached to one end of a stent (claim 44, upon which claims 45 and 46 depend) or a radiopaque tube disposed around a part of a stent (claim 47, upon which claims 48 and 49 depend). Instead, the first cited passage of Piplani describes a graft body in which markers are "secured to the fabric of the graft by suitable means such as Dacron sutures." Column 5, lines 21-25 of Piplani. The second passage from Piplani cited in the Office Action relates to markers on the tubular member 188 within a balloon catheter. For these additional reasons, a *prima facie* case of obviousness has not been established.

Even if the proposed combination of references taught each element of the rejected claims (as it must to establish *prima facie* obviousness), there is no suggestion to combine

Wolff with Piplani in the manner suggested in the Office Action and to further modify the combination in such a way as to arrive at applicants' claimed invention. The U.S. Court of Appeals for the Federal Circuit has stated that "[t]he mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." In re Fritch, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992) (citing In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984)).

For the foregoing reasons, withdrawal of the rejection of claims 45, 46, 48, and 49 based on the proposed combination of Wolff and Piplani is respectfully requested.

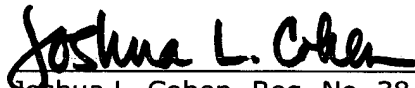
Appln. No.: 09/977,826
Amendment Dated
Reply to Office Action of January 26, 2004

BSI-010US4

Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that this application is now in proper form for allowance. A Notice of Allowance is therefore respectfully requested.

Respectfully submitted,



Joshua L. Cohen, Reg. No. 38,040
Attorney for Applicants

JLC/ap

Dated: April 26, 2004

Enclosure: Terminal Disclaimer w/Statement Under 37 CFR 3.73(b)

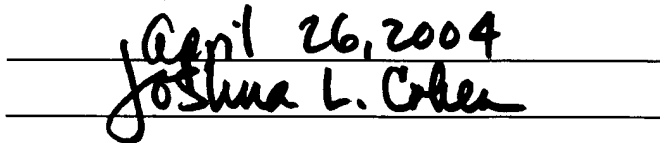
☒ P.O. Box 980
Valley Forge, PA 19482
(610) 407-0700

☐ P.O. Box 1596
Wilmington, DE 19899
(302) 778-2600

RECEIVED
APR 30 2004
TECHNOLOGY CENTER 3700

The Commissioner for Patents is hereby authorized to charge payment to Deposit Account No. **18-0350** of any fees associated with this communication.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:



AEP_I:\BSI\010US4\AMEND02.DOC